

FEDERAL REGISTER INDEX

January–August 2021

Food and Drug Administration

RULES

Electronic Import Entries; Technical Amendments – 17059 (*Apr 1*)
 Final Rule to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt:
 Milk and Cream Products and Yogurt Products – 31117 (*Jun 11*)
 Food Additives Permitted in Feed and Drinking Water of Animals:
 Guanidinoacetic Acid – 37037 (*Jul 14*)
 Selenomethionine Hydroxy Analogue – 37035 (*Jul 14*)
 Intended Uses – 41383 (*Aug 2*)
 Medical Devices:
 Medical Device Classification Regulations to Conform to Medical Software Provisions in the 21st Century Cures Act – 20278 (*Apr 19*)
 Technical Amendments – 17065 (*Apr 1*)
 New Animal Drug Applications:
 Beta-Aminopropionitrile Fumarate; n-Butyl Chloride; Cupric Glycinate Injection; Dichlorophene and Toluene; Orgotein For Injection; Tetracycline Tablets – 10818 (*Feb 23*)
 New Animal Drugs:
 Approval of New Animal Drug Applications – 17061 (*Apr 1*)
 Approval of New Animal Drug Applications; Change of Sponsor – 13181 (*Mar 8*)
 Approval of New Animal Drug Applications; Changes of Sponsorship; Change of Sponsor's Name and Address – 14815 (*Mar 19*)
 Withdrawal of Approval of New Animal Drug Applications – 10819 (*Feb 23*)
 Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs; Corrections – 17061 (*Apr 1*)
 Securing Updated and Necessary Statutory Evaluations Timely – 5694 (*Jan 19*)
 Securing Updated and Necessary Statutory Evaluations Timely; Administrative Delay of Effective Date; Correction – 15404 (*Mar 23*)
 Tobacco Products:
 Required Warnings for Cigarette Packages and Advertisements; Delayed Effective Date – 3793 (*Jan 15*); 36509 (*Jul 12*)
 Uniform Compliance Date for Food Labeling Regulations – 462 (*Jan 6*)

PROPOSED RULES

Filing of Color Additive Petition:
 Gardenia Blue Interest Group – 34664 (*Jun 30*)
 Piotrowska, PTY, LTD – 46803 (*Aug 20*)
 Filing of Food Additive Petition:
 Ag Chem Resources, LLC; Correction – 21984 (*Apr 26*)
 General Mills, Inc. – 21675 (*Apr 23*)
 Food Additive Petition:
 Canadian Oilseed Processors Association; Withdrawal – 24564 (*May 7*)

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals – 2674 (*Jan 13*); 10107 (*Feb 18*); 24628 (*May 7*); 24867 (*May 10*); 27092 (*May 19*); 30952 (*Jun 10*); 43665 (*Aug 10*)
 Agency Information Collection Activities; Proposals, Submissions, and Approvals:
 Accelerated Approval Disclosures on Direct-to-Consumer Prescription Drug Websites – 31323 (*Jun 11*)
 Adverse Experience Reporting for Licensed Biological Products; General Records – 10975 (*Feb 23*)
 Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives – 12690 (*Mar 4*); 36284 (*Jul 9*)
 Certification to Accompany Drug, Biological Product, and Device Applications or Submissions – 10104 (*Feb 18*)
 Class II Special Controls for Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests – 33708 (*Jun 25*)

Class II Special Controls Guidance Document: Labeling Natural Rubber Latex Condoms – 109 (*Jan 4*); 24633 (*May 7*)
 Class II Special Controls Guidance Document; Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Principle – 10108 (*Feb 18*)
 Current Good Manufacturing Practice for Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients – 30960 (*Jun 10*)
 Current Good Manufacturing Practice for Manufacturing, Processing, Packing, and Holding of Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients – 12466 (*Mar 3*)
 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human and Animal Food – 14436 (*Mar 16*)
 Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donation Testing, Donor Notification, and "Lookback" – 33713 (*Jun 25*)
 Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; Requirements for Donation Testing, Donor Notification, and "Lookback" – 10582 (*Feb 22*)
 Data to Support Drug Product Communications – 22970 (*Apr 30*)
 Data to Support Drug Product Communications as Used by the Food and Drug Administration – 5219 (*Jan 19*)
 Dispute Resolution Procedures for Science-Based Decisions on Products by the Center for Veterinary Medicine – 10581 (*Feb 22*)
 Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use – 12688 (*Mar 4*)
 Electronic User Fee Payment Request Forms – 22669 (*Apr 29*)
 Empirical Study of Promotional Implications of Proprietary Prescription Drug Names – 14440 (*Mar 16*)
 Environmental Impact Considerations – 47501 (*Aug 25*)
 Establishment and Operation of Clinical Trial Data Monitoring Committees – 22690 (*Apr 29*); 47505 (*Aug 25*)
 Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices – 10085 (*Feb 18*); 31316 (*Jun 11*)
 Expedited Programs for Serious Conditions; Drugs and Biologics – 10095 (*Feb 18*)
 Export Certificates – 2674 (*Jan 13*)
 Extralabel Drug Use in Animals – 2673 (*Jan 13*)
 Food Allergen Labeling and Reporting – 17843 (*Apr 6*)
 Food and Cosmetic Export Certificate Application Process – 14452 (*Mar 16*)
 Food and Cosmetic Export Certificates – 36282 (*Jul 9*)
 Food and Drug Administration Recall Regulations – 18543 (*Apr 9*)
 Food Labeling; Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments – 17607 (*Apr 5*)
 Food Safety; Federal-State Food Regulatory Program Standards – 26528 (*May 14*)
 Generic Clearance for Data To Support Cross-Center Collaboration for Social Behavioral Sciences Associated with Disease Prevention, Treatment, and the Safety, Efficacy, and Usage of Food and Drug Administration Regulated Products – 12484 (*Mar 3*)
 Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications – 31328 (*Jun 11*)
 Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications – 12952 (*Mar 5*)
 Human Drug Compounding, Repackaging, and Related Activities – 22674 (*Apr 29*)
 Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act – 47113 (*Aug 23*)
 Infant Formula Requirements – 21754 (*Apr 23*)
 Irradiation in the Production, Processing, and Handling of Food – 22688 (*Apr 29*)

Food and Drug Administration

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration – 27631 (May 21)

Medical Conference Attendees' Observations about Prescription Drug Promotion – 37160 (Jul 14)

Medical Device Labeling Regulations – 36752 (Jul 13)

Medical Device Recall Authority – 17610 (Apr 5); 41973 (Aug 4)

Medical Device Reporting – 22671 (Apr 29); 40593 (Jul 28)

Medical Devices; Device Tracking – 9514 (Feb 16)

Medical Devices; Humanitarian Use Devices – 11303 (Feb 24)

MedWatch; The Food and Drug Administration Medical Products Reporting Program – 34754 (Jun 30)

National Agriculture and Food Defense Strategy Survey – 104 (Jan 4); 30941 (Jun 10)

New Animal Drugs for Investigational Use – 30953 (Jun 10)

New Plant Varieties Intended for Food Use – 34765 (Jun 30)

Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities – 12692 (Mar 4)

Office of Management and Budget Approvals – 16221 (Mar 26)

Participation in the Food and Drug Administration Non-Employee Fellowship and Traineeship Programs – 1504 (Jan 8)

Pilot Survey to Develop Standardized Reporting Forms for Federally Funded Public Health Projects – 40853 (Jul 29)

Postmarketing Adverse Experience Reporting and Recordkeeping for Drug and Biological Products – 34759 (Jun 30)

Premarket Notification for a New Dietary Ingredient – 19623 (Apr 14)

Prescription Drug Advertising – 22686 (Apr 29); 39033 (Jul 23)

Prescription Drug Marketing; Administrative Procedures, Policies, and Requirements – 14128 (Mar 12); 33717 (Jun 25)

Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices – 11298 (Feb 24)

Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim "Healthy" on Packaged Foods – 24629 (May 7)

Recall Regulations – 1508 (Jan 8)

Recommended Content of Medical Product Communications That are Consistent with the Food and Drug Administration-Required Labeling and Recommendations for Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – 24868 (May 10)

Recommended Content of Medical Product Communications That Are Consistent with the Food and Drug Administration-Required Labeling and Recommendations for Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – 39035 (Jul 23)

Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim – 21748 (Apr 23)

Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution – 24871 (May 10)

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring – 19622 (Apr 14)

Regulations Under the Federal Import Milk Act – 31327 (Jun 11)

Request for Samples and Protocols – 14448 (Mar 16); 41488 (Aug 2)

Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice – 19270 (Apr 13)

Shortages Data Collections – 10972 (Feb 23); 28116 (May 25)

State Enforcement Notifications – 26046 (May 12)

Study of Disclosures to Healthcare Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug – 31318 (Jun 11)

Study of How Consumers Use Flavors to Make Inferences About Electronic Nicotine Delivery System Product Qualities and Intentions to Use (Phase 2) – 12468 (Mar 3)

Study of Multiple Indications in Direct-to-Consumer Television Advertisements – 12692 (Mar 4)

Substances Prohibited From Use in Animal Food or Feed – 17156 (Apr 1)

Survey of Drug Product Manufacturing, Processing, and Packing Facilities – 4098 (Jan 15)

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types – 10087 (Feb 18); 42845 (Aug 5)

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types – 14433 (Mar 16); 40856 (Jul 29)

Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics – 11300 (Feb 24)

Veterinary Feed Directive – 26532 (May 14)

Amendment of Temporary Marketing Permit:
Canned Tuna Deviating From the Standard of Identity – 12954 (Mar 5)

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2022 – 40595 (Jul 28)

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2022 – 39028 (Jul 23)

Authorization and Revocation of Emergency Use of Drugs during the COVID-19 Pandemic; Availability – 32938 (Jun 23)

Authorization of Emergency Use of Certain Medical Devices During COVID-19 – 21749 (Apr 23); 39040 (Jul 23)

Authorizations of Emergency Use of Certain Biological Products during the COVID-19 Pandemic – 42850 (Aug 5)

Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic; Availability – 28608 (May 27)

Authorizations of Emergency Use of Certain Drug and Biological Products During the COVID-19 Pandemic – 10290 (Feb 19)

Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic – 5200 (Jan 19)

Biosimilar User Fee Rates for Fiscal Year 2022 – 40567 (Jul 28)

Charter Renewal:
Advisory Committee; Medical Imaging Drugs Advisory Committee – 30953 (Jun 10)
Technical Electronic Product Radiation Safety Standards Committee – 10108 (Feb 18)

Charter Renewal:
Nonprescription Drugs Advisory Committee – 47646 (Aug 26)

Clarification to Food and Drug Administration Data Standards:
Data Standards; Requirement Begins for the Clinical Data Interchange Standards Consortium Version 1.1 of the Standard for Exchange of Nonclinical Data Developmental and Reproductive Toxicology Implementation Guide and Version 1.6 of the Study Data Tabulation Model – 12951 (Mar 5)

Concept Paper:
Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use In or On Feed – 1979 (Jan 11)

Determination of Regulatory Review Period for Purposes of Patent Extension:
AJOVY – 36285 (Jul 9)
AXONICS – 34757 (Jun 30)
BALVERSA – 34764 (Jun 30)
BARHEMSYS – 35803 (Jul 7)
BAROSTIM NEO – 15950 (Mar 25)
BEOVU – 35805 (Jul 7)
BRAVECTO; Correction – 31318 (Jun 11)
EVENITY – 30942 (Jun 10)
FETROJA – 34762 (Jun 30)
GIVLAARI – 32936 (Jun 23)
GORE CARDIOFORM ASD OCCLUDER – 34023 (Jun 28)
Hintermann Series H3 Total Ankle Replacement System – 14445 (Mar 16)
MAYZENT – 30949 (Jun 10)
OCS Lung System – 14455 (Mar 16)
OPTIMIZER – 30957 (Jun 10)
OXBRYTA – 34767 (Jun 30)
PIQRAY – 36142 (Jul 8)
POLIVY – 34768 (Jun 30)
SARCLISA – 30950 (Jun 10)
Smallpox and Monkeypox Vaccine, Live – 34018 (Jun 28)
SPRAVATO – 30955 (Jun 10)
TAZVERIK – 34022 (Jun 28)
TURALIO – 32950 (Jun 23)
WAKIX – 30947 (Jun 10)
XPOVIO – 30945 (Jun 10)
ZEPHYR ENDOBRONCHIAL VALVE IMPLANT – 35807 (Jul 7)
ZOLGENSMA – 33307 (Jun 24)

Determination that Products Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness:
ATROVENT (Ipratropium Bromide) Metered Spray, 0.021 Micrograms/Spray and 0.042 Micrograms/Spray – 30321 (Jun 7)
CECLOR CD (Cefaclor Extended-Release Tablets) 375 Milligrams and 500 Milligrams – 40587 (Jul 28)
CUTIVATE (Fluticasone Propionate) Ointment, 0.005 Percent – 17159 (Apr 1)
EFUDEX (Fluorouracil) Topical Solution, 5 Percent – 40566 (Jul 28)

- ISOPTIN (Verapamil Hydrochloride) Tablets 40 Milligrams, 80 Milligrams, and 120 Milligrams, and CALAN (Verapamil Hydrochloride) Tablets, 40 Milligrams, 80 Milligrams, 120 Milligrams, and 160 Milligrams – 27092 (May 19)
- MANGANESE SULFATE, Injectable, Equivalent 0.1 Milligram Manganese/Milliliter – 28112 (May 25)
- ORTHO-CEPT (Desogestrel-Ethinyl Estradiol) 21- and 28-Day Oral Tablets, 0.15 Milligram/0.03 Milligram – 47118 (Aug 23)
- OVIDE (Malathion) Lotion, 0.5%, – 26528 (May 14)
- QUELICIN PRESERVATIVE FREE (Succinylcholine Chloride) Injection, 20 Milligrams/Milliliter, 50 Milligrams/Milliliter, and 100 Milligrams/Milliliter – 30320 (Jun 7)
- SERENTIL (Mesoridazine Besylate) Tablets, 10 Milligrams, 25 Milligrams, 50 Milligrams, and 100 Milligrams – 17159 (Apr 1)
- Sodium Chloride 14.6 Percent Solution for Injection, 50 Milliequivalent/20 Milliliters, in Plastic Containers – 22059 (Apr 26)
- STROMEKTOL (Ivermectin) Tablets, 6 Milligrams – 37158 (Jul 14)
- Determination:
SANDOSTATIN (Octreotide Acetate) Injection, Equal to 0.2 Milligrams Base/Milliliter and Equal to 1 Milligrams Base/Milliliter, Was Not Withdrawn from Sale for Reasons of Safety or Effectiveness – 29585 (Jun 2)
- Drug Products Not Withdrawn from Sale for Reasons of Safety or Effectiveness:
ARALEN (Chloroquine Phosphate) Oral Tablets, 500 Milligrams – 1516 (Jan 8)
- Drug Review Timeline Transparency:
Revocation of Statement of Policy; Withdrawal – 23389 (May 3)
- Electronic Common Technical Document; Data Standards; Specifications for Electronic Common Technical Document Validation Criteria – 48431 (Aug 30)
- Electronic Common Technical Document; Data Standards; Specifications for the Electronic Common Technical Document Validation Criteria – 47504 (Aug 25)
- Electronic Study Data Submission; Data Standards:
Support and Requirement Begin for Study Data Tabulation Model Version 1.8 With Standard for Exchange of Nonclinical Data Implementation Guide--Animal Rule Version 1.0; Correction – 30960 (Jun 10)
- Electronic Study Data Submission; Data Standards; Technical Rejection Criteria for Study Data Effective Date – 40855 (Jul 29)
- Electronic Submissions:
Update to the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines; Technical Specification – 18541 (Apr 9)
- Eligibility for the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species – 33303 (Jun 24)
- Environmental Impact Statements; Availability, etc.:
Certain Sunscreen Drug Products for Over-The-Counter Use – 26224 (May 13)
- Certain Sunscreen Drug Products for Over-the-Counter Use; Reopening of Comment Period – 33712 (Jun 25)
- Establishment of a Public Docket:
Best Practices for Development and Application of Disease Progression Models; Public Workshop – 11301 (Feb 24)
- Drug Products Approved in Abbreviated New Drug Applications Before the Enactment of the Hatch-Waxman Amendments – 44731 (Aug 13)
- Evaluation of Study Data Exchange Standards for Submission of Study Data to the Center for Veterinary Medicine – 31720 (Jun 15)
- Extension of the Period Before the Food and Drug Administration Intends to Begin Enforcing the Statutory 5 Percent Limit on Out of State Distribution of Compounded Human Drug Products – 43550 (Aug 9)
- FDA Drug Review Timeline Transparency; Statement of Policy – 4083 (Jan 15)
- Fee Rates under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021 – 16223 (Mar 26)
- Fee Rates under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021; Withdrawal – 550 (Jan 6)
- Filing of Food Additive Petition:
Biomin Holding GmbH – 35806 (Jul 7)
- Final Debarment Order:
Alec Burlakoff – 102 (Jan 4)
- Belen G. Ngo; Denial of Hearing – 41486 (Aug 2)
- Jacobo Geissler – 40592 (Jul 28)
- Jerrold Nichols Smith – 101 (Jan 4)
- Jonathan Doyle – 40063 (Jul 26)
- Joseph A. Rowan – 103 (Jan 4)
- Justin Ash – 40579 (Jul 28)
- Lawrence B. Ryan – 12482 (Mar 3)
- Mark Reinhard – 19625 (Apr 14)
- Matthew Hebert – 41042 (Jul 30)
- Michael Gurry – 12473 (Mar 3)
- Rick Shepard – 26523 (May 14)
- Sunrise Lee – 100 (Jan 4)
- Ursula Wing – 16226 (Mar 26)
- Vithal K. Patel; Denial of Hearing – 41483 (Aug 2)
- Food and Drug Administration Modernization Act:
Modifications to the List of Recognized Standards, Recognition List Number: 054 – 12476 (Mar 3)
- Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2022 – 40571 (Jul 28)
- Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2022 – 40575 (Jul 28)
- Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2022 – 40580 (Jul 28)
- Generic Drug User Fee Rates for Fiscal Year 2022 – 40582 (Jul 28)
- Guidance:
Abbreviated New Drug Applications for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of Recombinant Deoxyribonucleic Acid – 27446 (May 20)
- Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products – 27627 (May 21)
- Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications – 35304 (Jul 2)
- Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Principle – 30958 (Jun 10)
- Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products – 14454 (Mar 16)
- Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted under an Abbreviated New Drug Application – 47117 (Aug 23)
- Bispecific Antibody Development Programs – 28115 (May 25)
- Cancer Clinical Trial Eligibility Criteria: Approach to Available Therapy in Non-Curative Settings – 33710 (Jun 25)
- Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products – 33310 (Jun 24)
- Chemotherapy-Induced Nausea and Vomiting: Developing Drugs for Prevention – 27090 (May 19)
- Compliance Policy Guide Sec. 555.400 Aflatoxins in Human Food; Compliance Policy Guide Sec. 570.200 Aflatoxins in Brazil Nuts; Compliance Policy Guide Sec. 570.375 Aflatoxins in Peanuts and Peanut Products; and Compliance Policy Guide Sec. 570.500 Aflatoxins in Pistachio Nuts; Availability – 29267 (Jun 1)
- Core Patient-Reported Outcomes in Cancer Clinical Trials – 30944 (Jun 10)
- Coronavirus Disease 2019 – 106 (Jan 4); 10285 (Feb 19)
- COVID-19: Developing Drugs and Biological Products for Treatment or Prevention – 26050 (May 12)
- COVID-19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention – 33309 (Jun 24)
- Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act – 30056 (Jun 4)
- Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered to Be Soluble in Aqueous Media – 27633 (May 21)
- Development and Submission of Near Infrared Analytical Procedures – 43555 (Aug 9)
- Documents Related to Coronavirus Disease 2019 – 39048 (Jul 23)
- Documents Related to Coronavirus Disease 2019; Availability – 21744 (Apr 23); 28627 (May 27)
- Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification – 30054 (Jun 4)
- E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials; International Council for Harmonisation – 26047 (May 12)
- Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs – 37159 (Jul 14)

Food and Drug Administration

- Enforcement Policy Regarding Use of National Health Related Item Code and National Drug Code Numbers on Device Labels and Package – 27629 (May 21)
- Enhanced Drug Distribution Security at the Package Level under the Drug Supply Chain Security Act – 30053 (Jun 4); 41853 (Aug 3)
- Evaluating Cancer Drugs in Patients with Central Nervous System Metastases – 35305 (Jul 2)
- Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus – 27438 (May 20)
- Field Alert Report Submission: Questions and Answers – 39046 (Jul 23)
- Frequently Asked Questions; Statement of Investigator – 27449 (May 20)
- Human Gene Therapy for Neurodegenerative Diseases – 549 (Jan 6)
- Implanted Brain-Computer Interface Devices for Patients with Paralysis or Amputation - Non-Clinical Testing and Clinical Considerations – 27443 (May 20)
- International Council for Harmonisation Q12; Implementation Considerations for Food and Drug Administration-Regulated Products – 27437 (May 20)
- Investigational New Drug Submissions for Individualized Antisense Oligonucleotide Drug Products – 314 (Jan 5)
- M9 Biopharmaceutics Classification System-Based Biowaivers; International Council for Harmonisation – 26054 (May 12)
- Mouse Embryo Assay for Assisted Reproduction Technology Devices – 312 (Jan 5)
- Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases – 22213 (Apr 27)
- Nonmetastatic Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials – 43551 (Aug 9)
- Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations – 29789 (Jun 3)
- Oversight of Food Products Covered by Systems Recognition Arrangements – 36559 (Jul 12)
- Peripheral Vascular Atherectomy Devices; Premarket Notification Submissions – 27441 (May 20)
- Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including during the Public Health Emergency (COVID-19) – 10977 (Feb 23)
- Postmarket Surveillance under the Federal Food, Drug, and Cosmetic Act; Draft – 28602 (May 27)
- Premenopausal Women with Breast Cancer: Developing Drugs for Treatment – 33313 (Jun 24)
- Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order; Draft – 28630 (May 27)
- Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers – 30058 (Jun 4)
- Product-Specific Guidance for Cilastatin Sodium; Imipenem; Relebactam – 38102 (Jul 19)
- Product-Specific Guidance for Olodaterol Hydrochloride; Tiotropium Bromide – 40574 (Jul 28)
- Product-Specific Guidances – 15948 (Mar 25); 27447 (May 20); 47112 (Aug 23)
- Providing Regulatory Submissions in Alternate Electronic Format – 35302 (Jul 2)
- Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management; International Council for Harmonisation – 26043 (May 12)
- Q3D(R2)--Guideline for Elemental Impurities; International Council for Harmonisation – 26052 (May 12)
- Qualified Infectious Disease Product Designation--Questions and Answers – 26045 (May 12)
- Rabies: Developing Monoclonal Antibody Cocktails for the Passive Immunization Component of Post-Exposure Prophylaxis – 40851 (Jul 29)
- Reauthorization Act Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs – 28113 (May 25)
- Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to Be Available as Over-the-Counter – 31317 (Jun 11)
- Remanufacturing of Medical Devices – 33305 (Jun 24); 42843 (Aug 5)
- S11 Nonclinical Safety Testing in Support of Development of Pediatric Pharmaceuticals; International Council for Harmonisation – 26056 (May 12)
- S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals; International Council for Harmonisation – 26048 (May 12)
- Safer Technologies Program for Medical Devices – 547 (Jan 6)
- Safety and Performance Based Pathway Device-Specific Guidances – 48430 (Aug 30)
- Sponsor Responsibilities -- Safety Reporting Requirements and Safety Assessment for Investigational New Drug Application and Bioavailability/Bioequivalence Studies; Draft Guidance – 34020 (Jun 28)
- Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised) – 9508 (Feb 16); 36560 (Jul 12)
- Testing and Labeling Medical Devices for Safety in the Magnetic Resonance Environment – 27444 (May 20)
- Tobacco Product User Fees – 28604 (May 27)
- Unique Device Identification System; Form and Content of the Unique Device Identifier – 35802 (Jul 7)
- Guidance:
- Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens of Programmed Cell Death Receptor-1 or Programmed Cell Death-Ligand 1 Blocking Antibodies for Treatment of Patients with Cancer – 47649 (Aug 26)
- International Drug Scheduling:
- Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F-MDMB-BICA (4F-MDMB-BUTICA); Brorophine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut – 39038 (Jul 23)
 - Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F-MDMB-BICA (4F-MDMB-BUTICA); Brorophine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut; Reopening Comment Period – 45738 (Aug 16)
 - Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Isotonitazene; MDMB-4en-PINACA; CUMYL-PEGACLONE; Flubromazolum; Clonazolum; Diclazepam; 3 Methoxyphencyclidine; Diphenidine – 10097 (Feb 18)
- Issuance of Priority Review Voucher:
- Rare Pediatric Disease Product – 9514 (Feb 16); 14125, 14130 (Mar 12); 35307 (Jul 2)
- List of Bulk Drug Substances for Which There is a Clinical Need under the Federal Food, Drug, and Cosmetic Act – 15673 (Mar 24)
- List of Bulk Drug Substances under the Federal Food, Drug, and Cosmetic Act – 1515 (Jan 8)
- Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices from Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program – 4088 (Jan 15)
- Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices from Premarket Notification Requirements; Withdrawal of Proposed Exemptions – 20174 (Apr 16)
- Material Threat Medical Countermeasure Product:
- Issuance of Priority Review Voucher – 36752 (Jul 13)
- Medical Device User Fee Rates for Fiscal Year 2022 – 41477 (Aug 2)
- Medical Devices-Exemption From Premarket Notification; Powered Patient Transport, All Other Powered Patient Transport:
- Correction – 34770 (Jun 30)
- Medical Devices:
- Availability of Safety and Effectiveness Summaries for Premarket Approval Applications – 15686 (Mar 24)
 - Class I Surgeon's and Patient Examination Gloves – 20167 (Apr 16); 40061 (Jul 26)
 - Exemption from Premarket Notification: Powered Patient Transport, All Other Powered Patient Transport – 31722 (Jun 15)
 - Exemption from Premarket Notification; Powered Patient Transport, All Other Powered Patient Transport – 39047 (Jul 23)
- Meetings:

Advancing the Development of Pediatric Therapeutics Complex Innovative Trial Design; Public Workshop – 42849 (Aug 5)
 Animal Drug User Fee Act – 18989 (Apr 12)
 Animal Generic Drug User Fee Act – 18986 (Apr 12)
 Antimicrobial Drugs Advisory Committee – 41475 (Aug 2)
 Application for Approval To Market a New Drug – 9510 (Feb 16)
 Arthritis Advisory Committee – 16227 (Mar 26)
 Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee – 9512 (Feb 16)
 Cardiovascular and Renal Drugs Advisory Committee – 27626 (May 21)
 Cellular, Tissue and Gene Therapies Advisory Committee – 40059 (Jul 26)
 Circulatory System Devices Panel of the Medical Devices Advisory Committee – 2676 (Jan 13); 12483 (Mar 3); 35303 (Jul 2); 47648 (Aug 26)
 Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs; Workshop – 33312 (Jun 24)
 Development Considerations of Antimicrobial Drugs for the Treatment of Gonorrhea – 19271 (Apr 13)
 Endocrinologic and Metabolic Drugs Advisory Committee – 17165 (Apr 1)
 Financial Efficiency of Human Drug User Fee – 27089 (May 19)
 Fiscal Year 2021 Generic Drug Science and Research Initiatives Workshop; Public Workshop – 15683 (Mar 24)
 Food and Drug Administration Science Forum 2021; Public Workshop – 17164 (Apr 1)
 Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee – 31315 (Jun 11)
 General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee – 9513 (Feb 16); 47645 (Aug 26)
 Medical Device User Fee Amendments of Fiscal Years 2023 to 2027 Reauthorization – 10289 (Feb 19)
 Model Informed Drug Development Approaches for Immunogenicity Assessments; Workshop – 21753 (Apr 23)
 Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions; Public Workshop; Request for Comments – 20172 (Apr 16)
 Neurological Devices Panel of the Medical Devices Advisory Committee – 26524 (May 14)
 Oncologic Drugs Advisory Committee – 14125 (Mar 12)
 Oncologic Drugs Advisory Committee; Establishment of a Public Docket – 26526 (May 14)
 Patient Engagement Advisory Committee – 44028 (Aug 11)
 Patient-Focused Drug Development for Vitiligo – 4085 (Jan 15)
 Pediatric Advisory Committee – 43666 (Aug 10)
 Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee – 19272 (Apr 13)
 Pharmacy Compounding Advisory Committee – 24631 (May 7)
 Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine; A Risk Management Tool for Antimicrobial New Animal Drugs – 18988 (Apr 12)
 Potential Medication Error Risks with Investigational Drug Container Labels – 14457 (Mar 16)
 Prescription Drug User Fee Act – 4086 (Jan 15)
 Reauthorization of the Prescription Drug User Fee Act – 47316 (Aug 24)
 Science Advisory Board to the National Center for Toxicological Research Advisory Committee – 17609 (Apr 5)
 The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Reopening of the Comment Period – 15685 (Mar 24)
 Vaccines and Related Biological Products Advisory Committee – 9071 (Feb 11); 9506 (Feb 16); 27635 (May 21); 47314 (Aug 24)
 Modifications to the List of Recognized Standards:
 Recognition List Number: 055 – 22678 (Apr 29)
 Modified Risk Tobacco Product Application:
 IQOS 3 System Holder and Charger Submitted by Philip Morris Products SA – 26530 (May 14)
 New Drug Application; Proposal to Refuse:
 Sotagliflozin Oral Tablets, 200 Milligrams and 400 Milligrams; Hearing – 12471 (Mar 3)
 New Drug Applications:
 Lavipharma Laboratories, Inc., et al.; Withdrawal of Approval – 18542 (Apr 9)
 Morton Grove Pharmaceuticals Inc. et al.; Withdrawal of Approval of Seven – 12950 (Mar 5)
 Order:
 Thomas J. Whalen: Final Debarment – 16222 (Mar 26)

Outsourcing Facility Fee Rates for Fiscal Year 2022 – 40588 (Jul 28)
 Post-Marketing Pediatric-Focused Product Safety Reviews – 43667 (Aug 10)
 Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use in or on Feed:
 A Concept Paper – 10979 (Feb 23)
 Prescription Drug User Fee Rates for Fiscal Year 2022 – 45732 (Aug 16)
 Regulatory Review Period for Purposes of Patent Extension:
 BioMimics 3D Vascular Stent System – 17167 (Apr 1)
 IBSRELA – 17157 (Apr 1)
 TPOXX – 17160 (Apr 1)
 Request for Applications:
 New Members of the Clinical Trials Transformation Initiative/Food and Drug Administration Patient Engagement Collaborative – 39044 (Jul 23)
 Request for Comments:
 Listing of Patent Information in the Orange Book – 14450 (Mar 16)
 Request for Comments:
 Evaluation of Study Data Exchange Standards for Submission of Study Data to the Center for Veterinary Medicine – 47647 (Aug 26)
 Request for Information:
 Evaluating the Clinical Pharmacology of Peptides; Establishment of a Public Docket – 26525 (May 14)
 Genus Medical Technologies, LLC Versus Food and Drug Administration – 43553 (Aug 9)
 Request for Nominations:
 Device Good Manufacturing Practice Advisory Committee – 12696 (Mar 4)
 Individuals and Consumer Organizations for Advisory Committees – 1510 (Jan 8); 15944 (Mar 25)
 National Mammography Quality Assurance Advisory Committee – 1507 (Jan 8)
 Voting Members on a Public Advisory Committee; Blood Products Advisory Committee – 16220 (Mar 26)
 Request for Notification of Stakeholder Intention to Participate:
 Animal Drug User Fee Act; Stakeholder Consultation Meetings on the Animal Drug User Fee Act Reauthorization – 18991 (Apr 12)
 Animal Generic Drug User Fee Act; Stakeholder Consultation Meetings on the Animal Generic Drug User Fee Act Reauthorization – 18987 (Apr 12)
 Request for Proposals:
 Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation – 6343 (Jan 21)
 Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation; Withdrawal – 36283 (Jul 9)
 Requests for Nominations:
 Individuals and Consumer Organizations for Advisory Committees – 44024 (Aug 11)
 Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID-19 – 48736 (Aug 31)
 Revocation of Authorization of Emergency Use of Certain Medical Devices During COVID-19 – 48712 (Aug 31)
 Revocation of Authorization:
 Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID-19; Availability – 28841 (May 28)
 Emergency Use of a Medical Device During COVID-19 – 17162 (Apr 1)
 Emergency Use of a Medical Device During COVID-19; Availability – 28849 (May 28)
 Termination of Unapproved Drugs Initiative; Request for Information Regarding Drugs Potentially Generally Recognized as Safe and Effective; Withdrawal – 28605 (May 27)
 TG United, Inc., et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications:
 Correction – 17165 (Apr 1)
 Withdrawal of Approval of 21 Abbreviated New Drug Applications:
 Morton Grove Pharmaceuticals, Inc., et al.; Correction – 36562 (Jul 12)
 Withdrawal of Approval of 27 Abbreviated New Drug Applications:
 TG United Inc., et al. – 4081 (Jan 15)
 Withdrawal of Approval of 85 Abbreviated New Drug Applications:
 Actavis Elizabeth, LLC, et al. – 40850 (Jul 29)
 Withdrawal of Approval of Abbreviated New Drug Application:
 Breckenridge Pharmaceutical, Inc., Solifenacin Succinate Tablets, 5 Milligrams and 10 Milligrams – 48429 (Aug 30)
 Withdrawal of Approval of Abbreviated New Drug Applications:
 VistaPharm, Inc., et al. – 14130 (Mar 12)
 Watson Laboratories, Inc., et al. – 33718 (Jun 25)

Food and Drug Administration

Withdrawal of Approval of New Drug Applications:

Bacitracin for Injection – 14127 (*Mar 12*)
Bristol-Meyers Squibb Company, et al. – 14447 (*Mar 16*)
Fresenius Kabi USA, LLC, et al. – 40591 (*Jul 28*)
Lederle Laboratories et al. – 26058 (*May 12*)
Lederle Laboratories et al.; Correction – 31722 (*Jun 15*)
Morton Grove Pharmaceuticals Inc., et al.; Correction – 27440 (*May 20*)

Withdrawal of Approval of Three New Drug Applications:

PolyMedica Industries Inc., et al. – 12474 (*Mar 3*)

Withdrawal of Drug Products from Sale for Reasons of Safety or Effectiveness:

BELVIQ (Lorcaserin Hydrochloride) Tablets, 10 Milligrams, and BELVIQ XR (Lorcaserin Hydrochloride) Extended-Release Tablets, 20 Milligrams – 12697 (*Mar 4*)

Withdrawal of Drug Products from Sale for Reasons other than Safety or Effectiveness:

AVACLYR (Acyclovir Ophthalmic Ointment), 3 Percent – 27436 (*May 20*)
Folic Acid, Oral Tablets, 1 Milligram, and Other Drug Products – 15682 (*Mar 24*)
NIPRIDE RTU (Sodium Nitroprusside), 10 Milligrams/50 Milliliters (0.2 Milligrams/Milliliters) – 14451 (*Mar 16*)
NORMODYNE (labetalol hydrochloride) Injection, 5 Milligrams per Milliliter – 27440 (*May 20*)
NYMALIZE (nimodipine), Oral Solution, 3 Milligrams/Milliliter – 9944 (*Feb 17*)

Withdrawal of Drug Products from Sale for Reasons Other Than Safety or Effectiveness:

VOTRIENT (Pazopanib Hydrochloride) Tablets, 400 Milligrams – 42843 (*Aug 5*)